Genetically-Modified Work

1. What rationales underlie the decision for the FDA to oversee genetically-modified mosquitoes?
    a. In particular, why was the FDA – rather than the EPA – doing the environmental assessment?
        i. FDA has asserted jurisdiction over the Oxitec mosquito as a "new animal drug" and because FIFRA excludes new animal drugs from the definition of "pesticide" EPA has no regulatory authority over the mosquito. However, tThe EPA, CDC and FDA all worked in coordination on the environmental assessment and finding of no significant impact documents for the Oxitec, Ltd OX513A genetically engineered *Aedes aegypti* mosquito. EPA and FDA-CVM work under a memorandum of understanding to specifically address the assessment of the Oxitec product. While FDA has taken the lead in reviewing this genetically engineered mosquito, EPA and CDC have acted as technical consultants on the assessment.
    b. Does the EPA agree with the FDA conclusion that investigational use of the Oxitec mosquitoes "would not result in significant effects on the quality of the human environment?"
        i. Yes, the EPA Office of Pesticide Programs ~~has signed off on~~reviewed the documents indicating that the environmental field evaluation of the OX513A mosquito as proposed is adequate to allow for field testing. EPA-OPP is in agreement with FDA-CVM and CDC on the primary finding of the EA and FONSI. We do not feel any significant effects on human health or environmental impact will result from the field testing as described.
    c. What is the extent of coordination the EPA and FDA on Oxitec mosquitoes, given the EPA's experience in other GM pest control work?
        i. EPA and FDA maintain a close coordination via meetings, conference calls and e-mail exchange on matters associated with the regulation of the OX513A mosquito. FDA-CVM, CDC and EPA-OPP personnel all commented on drafts of the EA and FONSI documents followed by conference calls to establish final edits for the documents. EPA has attended meetings with Oxitec, FDA-CVM and CDC to discuss the details of the product and the proposed field trial. It should be noted that the FDA and EPA have committed, along with USDA, to examining their regulatory structures with the goal of clarifying how the Federal government will regulate genetically engineered insects in an integrated and coordinated fashion to cover the full range of potential products. The agencies are working to better align their responsibilities

over genetically engineered insects with their traditional oversight roles, for example, considering mechanisms that would enable EPA to regulate genetically engineered mosquitoes under FIFRA when the developer claims they are intended to control population levels (pesticidal), and FDA to regulate them under FD&C Act when the developer makes a disease claim (animal drug). (National Strategy for Modernizing the Regulatory System for Biotechnology Products at [HYPERLINK "https://www.whitehouse.gov/sites/default/files/microsites/ostp/biotech_national_strategy_final.pdf"]). FDA and EPA are currently coordinating their efforts to meet this commitment as both FDA and EPA regulate products intended for use in or on animals. FDA is charged with protecting the public health by, among other things, ensuring that animal drugs are safe and effective [21 U.S.C. §393(b)(2)(B)]; under FIFRA, EPA is charged with protecting human health and the environment by ensuring registered pesticide products, when used according to the label directions, result in no unreasonable adverse effects to man or the environment. [7 U.S.C. § 136a(c)(5)].